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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,250	08/20/2003	Muktar A. Mahajan	57953/1151	7913

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EXAMINER	
GUIDRY, GUY L	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/645,250	MAHAJAN ET AL.	
	Examiner	Art Unit	
	Guy Guidry, Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-91* is/are pending in the application.

4a) Of the above claim(s) *8-91* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/13/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This is a First Office Action on the Merits. Receipt is acknowledged of a Response filed 10 March 2006 to the Restriction Requirement mailed 30 November 2005. Claims 1-91 are currently pending in this application. Claims 1-7 are under consideration in this action.

Election/Restrictions

Applicant's election of Group I (claims 1-7, SEQ ID NOs: 1, 4 and 3), with traverse in the reply filed on 10 March 2006 is acknowledged. Claims 8-91 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim.

Applicant has traversed the restriction requirement on the basis that that the claims are closely related and therefore require common areas of search and consideration. Applicant further argues that at the very least, the restriction between Group 1 and Group 2 is improper and should be withdrawn because the molecules of Group 1 encode the NIF-I protein, while the nucleic acid molecules of Group 2 encode the N1F-2 protein where the N1F-2 protein is an alternatively spliced form of NIF-1 and are closely related as demonstrated by the fact that the nucleic acid molecules of Groups I and II are all classified in the restriction requirement as belonging to class 536, subclass 23.1 (¶3 of March 2006 Response).

Applicant's arguments have been considered and they are not persuasive. The nucleic acids of Group 1 and 2 are comprised of distinct structures (i.e., sequences)

thus are patentably distinguishable, therefore inventions in Group 1 and 2 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are defined by distinct nucleotide sequences that encode NIF-1 and an alternatively spliced product, NIF-2 (i.e., SEQ ID NO: 1 and SEQ ID NO: 5, respectively). Neither the claims nor the specification are directed to said NIF-1 and NIF-2 nucleic acids as being concomitantly utilized in the various methods disclosed. Further, since the sequences have distinct structures, each encodes a polypeptide by a different mode of operation. Moreover, a search of the varied and ever increasing in number sequence databases for one sequence would not yield the other. Thus, searching for the distinct nucleic acid sequences would be overly burdensome. As Applicant has suggested Groups 1 and 2 are more closely related in Applicant's opinion than the rest of the Groups are to each other and the Office finds that Groups 1 and 2 are unrelated, then the remaining groups also unrelated. Therefore, the requirement is still deemed proper and is made *FINAL.*

Priority

Applicants' claim for the benefit of a Provisional Application 60/405,752 application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. [1] as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/405,752 fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The provisional application does not provide a written description of the polynucleotide identified in claim 2 as Sequence ID NO: 4, a nucleotide sequence in which the region 5' to the start codon of the NIF-1 encoding nucleic acid (instant SEQ ID NO: 1) is truncated wherein the truncated region is not required for expression of the translated protein. Accordingly, claim 2 is not entitled to the benefit of the prior application.

Claim Objections

Claim 2 is objected to because of the following informalities: the claim contains two parts labeled 4). Were the elements of the claim properly enumerated, the claim would contain 7 numbered parts.

In addition the claim is objected to for wording in part 3), wherein an isolated nucleic acid molecule "encodes an amino acid having SEQ ID...". Amending the claim to recite "encodes an amino acid sequence having SEQ ID..." would be remedial for this

objection.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 as written, it is not clear as to which of the two following possible interpretations of the claim Applicant intends

-that the claimed nucleic acid molecule has either all of the sequences of parts 1), 2), 3) and 5), or those of part 6)

or

- that the isolated nucleic acid molecule has either one sequence selected from parts 1), 2), 3) and 5), or those of part 6).

As two alternative interpretations are possible, the claim is indefinite.

Claim 3 is indefinite because it is not possible to distinctly determine the structural relationship between the claimed nucleic acid molecule and the linked 5' and 3' regulatory regions. For example, one interpretation of the claim is that the regions may be operably linked to each end of the nucleic acid molecule. Other interpretations include that the regulatory regions are derived from 5' and 3' sequences of the a native

nucleic acid construct and are both to be operable linked to the 5' end of the nucleic acid molecule, or conversely both regions operably linked to the 3' end of the nucleic acid molecule. Further, the operably linked region may be located somewhere within the 5' and 3' ends of the isolated nucleic acid. Therefore, the claim is indefinite.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As noted in the preceding section, claim 2 is indefinite for having multiple possible interpretations. In the interest of furthering prosecution, the Office is interpreting claim 2 as an isolated nucleic acid molecule having a sequence comprising SEQ ID NO: 1, or sequences that hybridize to SEQ ID NO: 1.

The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 and dependent claims 3-7 are drawn to *any* isolated nucleic acid molecule encoding a protein that modulates transcription in a cell, 5' and 3' regulatory

regions and vector and host cells comprising the nucleic acid molecule. Further, claim 2 is literally directed to *any* amino acid sequence of *any* size encoded by *any* nucleic acid that hybridizes under stringent conditions to the nucleic acid encoding SEQ ID NO: 1 that must correlate to the functionality of encoding a protein that modulates transcriptional activation in a cell.

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, (CAFC) 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("The description must clearly allow persons of ordinary skill in the art to recognize that (the inventor) invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious" and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Supra*, *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966. Furthermore, the Guidelines for Written Description state, "The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art" (Federal Register/ Vol. 66, No. 4/Friday, January 5, 2001/Notices, column 1, page 1105). The Guidelines further state, "[t]he claim as a whole, including all limitations found in the preamble, the transitional phrase, and the body of the claim, must be sufficiently supported to satisfy the written description

requirement" (at page 1105, center column, third full paragraph). In sum, an applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations. *Supra*, *Lockwood*, 107 F.3d at 1572, 41 USPQ2d 1961 (at 1966).

Applicant is claiming a truly enormous breadth of possible nucelic acid molecules. The number of human nucleic acids encoding proteins that modulate transcriptional activation number on the hundreds, if not thousands of sequences. The instant disclosure is devoted to one such molecule NIF-1. With respect to sequence, the critical or essential elements are at minimum the minimal or conserved nucleic acid sequences (i.e., structures) that correlate to NIF-1 functionality and hybridize to any portion of the nucleic acid encoding the protein (i.e., DNA of SEQ ID NO: 1). The only disclosed embodiment is that of NIF-1. No additional structures are identified nor is additional evidence presented in the specification that clarifies or identifies what particular sequences within SEQ ID NO: 1 are conserved or necessary so as to correlated to NIF-1 functionality. In fact, the number of potential species encompassed by the claimed genus is further amplified insofar as the claims are directed to any functionality that comprises modulating transcriptional activation. Therefore, the required level of description in the specification or in the relevant art is increased even to an even higher level. Given that the instant disclosure provides a single example for such a tremendously large genus of structures, there is a notable gap in the specification regarding description of sufficient or representative number of embodiments.

In sum, given the very limited disclosure of a single species, given the enormous breadth of the structures necessary to practice, and encompassed by, the rejected claims, and the skilled artisan would not have been able to envision a sufficient number of specific embodiments to described the broadly claimed genus of a nucleic acid molecule encoding a protein that modulates transcriptional activation or nucleic acids that hybridize to SEQ ID NO: 1 under stringent conditions.

Moreover, an applicant claiming a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from other species. Therefore, the skilled artisan would reasonably have concluded that applicants were not in possession of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Li et al. (Molecular and Cellular Biology ,1999, 19(10): 7197-7202, of record in the IDS filed February 2006).

Li et al. teach an a isolated human nucleic acid molecule encoding a nuclear receptor coactivator NRIF3 that interacts with hormone receptors in receptor-mediated transcriptional activation (see the Abstract and p. 7193, col. 1, section titled "Cloning of NRIF3"), meeting the limitations of claim 1. The nucleic acid is ligated into cloning and expression vectors (see especially p. 7192, col. 2, ¶¶2-3), meeting the limitations of claims 4 and 3, where the expression vector is interpreted to contain regulatory regions both 5' and 3' to the inserted NRIF cDNA. The NRIF3 vector is transfected into HeLa cells (see p. 7194, Figure 3), meeting the limitations of claims 5-7. Further, the hybridization stringency recited in part 6) of claim 2 is very low and does not require any particular degree of hybridization (i.e., even a low level of hybridization meets the claim limitations). Absent evidence to the contrary, one would expect some non-specific hybridization to occur between the nucleic acid taught by Li et al. and the instant sequences under the conditions recited in claim 2. The Office does not have the facilities for examining and comparing Applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 USPQ 1302, 1303 (BPAI 1993), *In re*

Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ2 d 1922, 1923 (BPAI 1989). Thus, Li et al. fully anticipate instant claims 1-7.

Claims 1-7 are is rejected under 35 U.S.C. 102(e) as being anticipated by Tang et al. US Patent 6,783,969 (hereinafter Tang).

Tang teaches a human polynucleotide sequence SEQ ID NO: 67 with 96.9% identity to instant SEQ ID NO: 1, Due to the high degree of similarity between the reference and instant sequences, it is assumed that the protein encoded by the reference sequence has the function of modulating transcriptional activation (thus meeting the limitations of claim 1 and the 85% similar to SEQ ID NO: 1 part 5 of claim 2). The polynucleotide may be cloned into a vector (where an expression vector is known to a person of skill in the art to have regulatory regions 5' and 3' to the cloned insert, and see especially col. 15, ¶3 of Tang) and host cells transformed with the polynucleotide, including non-human mammals (see especially col. 29, ll. 48-50), meeting the limitations of claims 3-7. The Office does not have the facilities for examining and comparing Applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 USPQ 1302, 1303 (BPAI 1993), *In re Best*, 562

F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ2 d 1922, 1923 (BPAI 1989).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Guy Guidry, Ph.D. whose telephone number is 571-272-7928. The examiner can normally be reached on Monday through Friday 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Guy Guidry, Ph.D.

Examiner

Art Unit 1636

DANIEL M. SULLIVAN
PATENT EXAMINER